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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 10/679,376 | 10/07/2003 | Jean Gobert | 2003-1412 | 4286 |

7590 05/18/2004

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| EXAMINER | |
|---|---|
| BERNHARDT, EMILY B | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1624 | |

DATE MAILED: 05/18/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/679,376 | GOBERT, JEAN | |
| | Examiner | Art Unit | |
| | Emily Bernhardt | 1624 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) 1-9 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-9 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☒ Certified copies of the priority documents have been received in Application No. 08/207,096.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 10/7/2003
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

The abstract of the disclosure is objected to because it does not describe the invention currently being claimed. Correction is required. See MPEP § 608.01(b).

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 1-9 are rejected under 35 U.S.C. 102(b) as being anticipated by Cossement (GB'321) and citing Merck Index and Baltes (US'358) as supplementary evidence of what Cossement teaches. The GB reference discloses the preparation of instant compound. See eg.2, p.10 in which optical rotation is

reported. The compound is stated to be the optical isomer of a known racemate,ceterizine, which it is stated is already known in the art for various uses including treating allergies. See p.1 of the GB document. Merck and Baltes are cited as evidence that known uses of ceterizine prior to Cossement's publication include uses recited herein. See in Baltes col.14 which discusses various uses for his compounds which include ceterizine also described in col.1 and 2. In Merck see the entry for ceterizine which includes treating allergy,asthma. All the claimed uses are within either of these two references. Column 14 in Baltes also discusses various forms of administration as well as dosage ranges that are recited in claims 4-9. The narrow disclosure in Cossement (cetirizine and its two isomers) constitutes an adequate written description of instant isomer for aforementioned uses claimed herein. Note In re Schaumann 197 USPQ 5.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter

pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cossement (GB'321), Baltes and Merck Index. The teachings of the above references as discussed in the above 102 rejection are incorporated herein. If the teaching of Cossement is deemed too broad to constitute an anticipation for uses claimed herein, use of instant isomer for treating allergies, inflammation and asthma would be an obvious expedient given its very close structural similarity to the racemate and the fact that one skilled in the art would recognize the existence of such isomers and be able to prepare such employing known procedures such as the one admitted to be old in the specification , p.7 last paragraph as well as that disclosed in GB'321. There is case law regarding the patenting of a component of an old mixture. See Pfizer v. International Rectifier 190 USPQ 273; Eli Lilly v. Generix 174 USPQ 65 and In re Adamson 125 USPQ 233. In another case In re Volwiler 46 USPQ 137 the requirement for patentability of an isolated highly pure component from a mixture was deemed to be possession of unexpectedly different properties than that of the mixture. Also see In re May 197 USPQ 601 in which the non-addictive nature of the appealed isomer(s) was not a property known for related compounds but of long felt need in the art and so this combined with

analgesic activity was deemed an unexpected result. See also Sterling Drug v. Watson 108 USPQ 37. Thus it would have been obvious to one skilled in the art at the time the invention was made to expect instant isomers to also possess the uses taught or admitted to be old in the prior art in view of the well known knowledge of stereoisomerism and the expectation that at least one of a pair is expected to retain the activiy of the racemic form as discussed above.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); In re Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-9 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims of U.S. Patent No. 4525358. Although the conflicting claims are not identical, they are not patentably distinct from each other because they read on the same uses claimed herein employing among other compounds, the corresponding racemate of instant compound which is an obvious variant to that employed herein as discussed in the above rejection.

Commonly assigned 4525358, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee is required under 37 CFR 1.78(c) and 35 U.S.C. 132 to either show that the conflicting inventions were commonly owned at the time the invention in this application was made or to name the prior inventor of the conflicting subject matter. Failure to

comply with this requirement will result in a holding of abandonment of the application.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g).

Claims 1-9 are rejected under 35 U.S.C. 102(e) as being anticipated by Gray (US'183). Gray applied as of its effective filing date of 9/24/92 discloses (+) cetirizine for uses claimed herein. See columns 3 -5 which list various allergies,inflammation and asthma and column 6 which describes various forms of administration and dosages. The claims are directed to treating certain forms of urticaria which result from allergies. Note MPEP 2306 and 2307.

All references applied above have been cited and provided by applicant and/or the examiner in previous parents.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Emily Bernhardt whose telephone number is (571) 272-0664.

If attempts to reach the examiner by phone are unsuccessful, the supervisor for AU 1624, Dr. Mukund Shah, can be reached at (571)272-0674.

The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

E Bernhardt

**EMILY BERNHARDT**

**PRIMARY EXAMINER**

**Group 1600**